THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 34

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte STEPHEN H. HUGHES, RAMESH KUMAR
and JOHN BRUMBAUGH

Appeal No. 95-2215
Application 07/920,013[1]

ON BRIEF

Before WILLIAM F. SMITH, ELLIS and ROBINSON, Administrative Patent Judges.

ROBINSON, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1 - 10, which are all of the claims pending in this application.

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[1] Application for patent filed July 27, 1992. According to appellants, the application is a continuation of Application 07/484,573, filed February 26, 1990, now abandoned.

Independent claim 1 is illustrative of the subject matter on appeal and is reproduced below:

1. A method for detecting a DNA sequence comprising the steps of:

i) asymmetrically amplifying the DNA sequence so that one strand of the DNA sequence is amplified to a greater extent than the strands' (sic, strand's) complement forming an amplified DNA strand;

ii) hybridizing a fluorescently labeled probe to the amplified DNA strand wherein said fluorescently labeled probe is complementary to a segment of the amplified DNA strand, the hybridization being effected in solution and forming a fluorescently labeled hybridized probe;

iii) separating the fluorescently labeled hybridized probe from unhybridized labeled probe by electrophoresis; and

iv) detecting during electrophoresis the presence or absence of the fluorescently labeled hybridized probe by fluorescence detection, wherein the presence of the fluorescently labeled hybridized probe indicates the presence of said DNA sequence.

The references relied upon by the examiner are:

Mullis 4,683,202 Jul. 28, 1987

Gyllensten et al. (Gyllensten), " Generation of single-stranded DNA by the polymerase chain reaction and its application to direct sequencing of the HLA-DQA locus", Proc. Natl. Acad. Sci., vol. 85, pages 7652-7656, (October, 1988).

Brumbaugh et al. (Brumbaugh), " Continuous, on-line DNA sequencing using oligodeoxynucleotide primers with multiple fluorophors", Proc. Natl. Acad. Sci., vol. 85, pages 5610-5614, (August, 1988).

Grounds of Rejection

Claims 1-10 stand rejected under 35 U.S.C. § 103. As evidence of obviousness, the examiner relies on Gyllensten, Mullis, and Brumbaugh.

We reverse.

Background

At pages 2-3 of the specification, the applicants describe the invention as relating to a method of detecting a DNA sequence wherein the DNA sequence is asymmetrically amplified, hybridized, in solution, with a fluorescent labeled probe complementary to a segment of the amplified DNA sequence, followed by separation of the hybridized and non-hybridized product using electrophoresis. Applicants state that the labeled DNA is detected during the electrophoresis process in "real time."[2] Applicants also describe the use of the detection method for detecting the presence or absence of one or more pathogens in a test sample.

Discussion:

Claims:

Claim 1 is directed to a method of detecting a DNA sequence by asymmetrically amplifying the DNA sequence, hybridizing, in solution, a fluorescently labeled probe to the

[2]Applicants define "real time" as "no delay between the time of the electrophoretic run and the time the results are available." Specification, page 6, lines 32-35.

amplified DNA strand, wherein the labeled probe is complementary to a segment of the amplified DNA strand, separating the fluorescently labeled hybridized probe from unhybridized probe by electrophoresis, and detecting the presence or absence of the fluorescently labeled hybridized probe by fluorescence detection during the electrophoresis. Claims 5 and 8, the remaining independent claims, are directed to a method for detecting a DNA sequence to screen a sample for the presence or absence of a pathogen or several pathogens, respectively.

The rejection under 35 U.S.C. § 103

It is the initial burden of the patent examiner to establish that claims presented in an application for patent are unpatentable. In re Oetiker, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). We have carefully considered the evidence and discussion in support of the rejection presented by the examiner. However, a fair evaluation of the references, applicants' specification and consideration of the claimed subject matter as a whole, dictates a conclusion that arriving at the claimed method from the prior art teachings is not suggested by the record before us. When we view the three applied references, apart from appellants' disclosed invention, we find no reason, suggestion, or motivation to combine the references to arrive at the claimed invention. To establish a prima facie case of obviousness, there must be more than the demonstrated existence of all of the components. There must be some reason, suggestion, or motivation found in the prior art whereby a person of ordinary skill in the

field of the invention would make the substitutions required. That knowledge cannot come from the applicants' invention itself. Diversitech Corp. v. Century Steps, Inc., 850 F.2d 675, 678-79, 7 USPQ2d 1315, 1318 (Fed. Cir. 1988); In re Geiger, 815 F.2d 686, 688, 2 USPQ2d 1276, 1278 (Fed. Cir. 1987); Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1985). The extent to which such suggestion must be explicit in or may be fairly inferred from, the references, is decided on the facts of each case, in light of the prior art and its relationship to the invention. It is impermissible, however, simply to engage in a hindsight reconstruction of the claimed invention using applicants' specification as a template and selecting elements from references to fill the gaps. In re Gorman, 933 F.2d 982, 986-987, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991).

As pointed out by appellants (Brief, page 17):

> . . . there is no teaching or suggestion in the cited references to combine asymmetric amplification with solution phase hybridization with a fluorescently labeled probe.

We conclude that the rejection before us is predicated on impermissible hindsight and that it would not have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of the individual references to arrive at the DNA detection method of claims 1-10.

The rejection under 35 U.S.C. § 103 is reversed.

Summary

We reverse the rejection of claims 1-10 under 35 U.S.C. § 103.

REVERSED

WILLIAM F. SMITH Administrative Patent Judge	)	
JOAN ELLIS Administrative Patent Judge	)	BOARD OF PATENT APPEALS AND INTERFERENCES
DOUGLAS W. ROBINSON Administrative Patent Judge	)	

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